REMARKS

The foregoing amendments and the following remarks are responsive to the January 23, 2009 Office Action (the "Office Action").

Claim Rejections – 35 U.S.C. 102 – Claims 14, 19, and 21-23:

The Examiner rejected Claims 14, 19, and 21-23 under 35 U.S.C. 102(b) as being anticipated by International Application Publication No. WO 84/01904 ("Swanbeck"). Respectfully stated, none of Claims 14, 19, or 21-23 is anticipated by Swanbeck because Swanbeck does not show every element of each claim arranged as in each claim. *See* MPEP § 2131. Moreover, as discussed below, Swanbeck also does not render any of these claims obvious.

Claim 14

Regarding Applicants' amended Claim 14, respectfully stated, Swanbeck does not disclose or suggest, inter alia, a method of treating a wound, comprising: providing a conformable wound dressing having a cover configured to form a relatively fluid-tight seal around at least a portion of a wound; providing an apparatus for irrigating and/or cleansing a wound comprising: at least one inlet pipe configured to communicate with the cover and configured to provide a fluid conduit so that fluid can flow into the cover; at least one outlet pipe configured to communicate with the cover and configured to provide a fluid conduit so that fluid can flow out of the cover, wherein the fluid in the cover comprises physiologically active components; pumping fluid through at least the inlet pipe, the cover, and the outlet pipe; cleansing the fluid that flows out of the cover; ***regulating the fluid that flows out of the cover so that*** a portion of the fluid that flows out of the cover comprising physiologically active components is recirculated back to the cover after being cleansed and ***a portion of the fluid that flows out of the cover is bled through a bleed mechanism and is provided to a waste reservoir***; and heating the fluid before the fluid enters the cover ***to maintain the wound at an approximately normothermic range to optimize the metabolic activities of the physiologically active components within the cover and promote wound healing***.

As discussed and agreed to during the interview, Swanbeck does not disclose or suggest regulating the fluid that flows out of the cover so that … a portion of the fluid that flows out of

the cover is bled through a bleed mechanism and is provided to a waste reservoir, as set forth in Claim 14.

Further, Applicants submit that Swanbeck does not disclose or suggest heating the fluid before the fluid enters the cover to maintain the wound at an approximately normothermic range to optimize the metabolic activities of the physiologically active components within the cover and promote wound healing. The Office Action points to Swanbeck at page 4, lines 3-5 for this limitation. This portion of Swanbeck states that "the treatment solution may be placed in thermostatically regulated water bath to ensure a certain temperature of the treatment solution." Applicants submit that Swanbeck does not, at the above-referenced portion or otherwise, disclose or suggest that the thermostatically regulated water bath is configured to maintain the wound at an approximately normothermic range to optimize the metabolic activities of the physiologically active components within the cover and promote wound healing.

Pursuant to MPEP § 2131, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicants submit that Swanbeck does not expressly or inherently disclose, inter alia, this limitation. Swanbeck provides no disclosure or suggestion of any specific temperature ranges that the thermostatically regulated water bath could be maintained at. And, more to the point, Swanbeck provides no disclosure or suggestion of any specific temperature ranges that the thermostatically regulated water bath could be maintained at so as to maintain the wound at an approximately normothermic range.

Nor does Swanbeck discuss, suggest, or contemplate any of the many physiological benefits of increasing the temperature of the wound that are discussed in Applicants' specification and that support Claim 14. As stated in paragraphs 25-27 of the Applicants' published patent application (U.S. Patent Application Publication No. US 2007/0129707 A1), "it is generally believed that the body's own metabolic activities are at an optimum at or near the temperature naturally occurring in the relevant bodily part. Examples of metabolic molecules involved in tissue healing processes that are beneficial in promoting wound healing include enzymes, growth factors and anti-inflammatories, and other physiologically active components of the exudate from a wound. These are believed to act best at temperatures found in the relevant

bodily part and which they occur, varying between normal temperatures found at the body surface and those of the body core." Additionally, as stated in paragraph 28 of Applicants' Application Publication, "[w]ounds, and in particular chronic wounds, may have a lower temperature, e.g. 24 to 26° C., i.e. substantially below the optimum temperature. Thus, the temperature of the wound itself is deleterious to wound healing."

Although no such rejection is presently stated, Applicants respectfully submit that a rejection based on "optimum or workable ranges" based on Applicants' amended Claim 14 would be inappropriate where the prior art does not teach or suggest the desirability of the result achieved. As discussed in MPEP § 2144.05, "[a] particular parameter must first be recognized as a result-effective variable, i.e., a variable that achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." In re Antonie, 559 F.2d 618, 195 U.S.P.Q. 6 (CCPA 1977). Thus, for a rejection to be made based on optimum or workable ranges, the prior art must first identify the result which the variable achieves.

Without Swanbeck teaching the desired results of maintaining the wound at an approximately normothermic range (e.g., to optimize the metabolic activities of physiologically active components within the cover and promote wound healing, as set forth in Claim 14), the approximately normothermic range recited in Claim 14 would not have been merely a matter of design choice.

Thus, Swanbeck does not disclose, suggest, or appreciate, inter alia, heating the fluid before the fluid enters the cover to maintain the wound at an approximately normothermic range to optimize the metabolic activities of the physiologically active components within the cover and promote wound healing.

Claims 19 and 22

Regarding Applicants' amended Claim 19, Applicants respectfully submit that Swanbeck does not disclose or suggest, inter alia, an apparatus for irrigating, supplying thermal energy to, and cleansing wounds, comprising: a wound dressing comprising a backing layer configured to form a relatively fluid-tight seal around at least a portion of a wound; at least one inlet pipe configured to communicate with the backing layer and to provide a fluid conduit into the backing layer; at least one outlet pipe configured to communicate with the backing layer and to provide a

fluid conduit out of the backing layer; a fluid reservoir comprising irrigation fluid in fluid communication with the inlet pipe to supply irrigation fluid from the fluid reservoir into the backing layer; a fluid pump configured to pump fluid through at least the inlet pipe, the backing layer, and the outlet pipe; a fluid cleansing mechanism in fluid communication with the outlet pipe; a recirculation tube in fluid communication with the fluid cleansing mechanism configured to recirculate fluid cleansed by the fluid cleansing mechanism back into the inlet pipe, the fluid recirculation tube having ***a bleed valve to bleed fluid from the recirculation tube***, the recirculated fluid comprising physiologically active components; and a heat source configured to heat the fluid before the fluid enters the backing layer, ***the heat source configured so that the fluid maintains the wound at an approximately normothermic range to optimize the metabolic activities of physiologically active components within the backing layer and promote wound healing***.

As discussed and agreed to during the interview, Swanbeck does not disclose or suggest a bleed valve to bleed fluid from the recirculation tube, as set forth in Claim 19. Further, Applicants submit that Swanbeck does not disclose or suggest a heat source configured so that the fluid maintains the wound at an approximately normothermic range to optimize the metabolic activities of physiologically active components within the backing layer and promote wound healing, as set forth in Claim 19.

Regarding Claims 21-23, Claims 21 and 23 have been canceled. Applicants submit that Claim 22 is not anticipated or suggested by Swanbeck for at least the same reasons as for the claim or claims from which Claim 22 depends, and also because Claim 22 recites further patentable distinctions. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of Claims 14, 19, and 22.

Claim Rejections – 35 U.S.C. 103 – Claims 1, 2-5, 10-13, 15-17, 20:

The Examiner rejected Claims 1, 2-5, 10-13, 15-17 and 20 under 35 U.S.C. 103(a) as being unpatentable over Swanbeck. Claim 18 appears not to have been addressed by the Examiner in the Office Action, but Applicants address Claim 18 herein nonetheless. Respectfully stated, none of Claims 1, 2-5, 10-13, 15-18 and 20 is disclosed, suggested, or rendered obvious by Swanbeck.

Regarding Applicants' amended Claim 1, respectfully stated, Swanbeck does not disclose or suggest, inter alia, an apparatus for irrigating, supplying thermal energy to, and cleansing wounds, comprising a fluid flow path, comprising: a conformable wound dressing, comprising a backing layer which is capable of forming a relatively fluid-tight seal or closure over a wound and a wound-facing face, at least one inlet pipe passing through and/or under the wound-facing face and directly or indirectly communicating with at least a fluid reservoir, and at least one outlet pipe passing through and/or under the wound-facing face, wherein a relatively fluid-tight seal or closure is formed over the wound at the point at which each inlet pipe and each outlet pipe passes through and/or under the wound-facing face; a means for fluid cleansing in direct or indirect communication at least with the outlet pipe; and a fluid recirculation tube for directing cleansed fluid from the means for fluid cleansing back into the inlet pipe so that at least nutrients, molecules, factors, physiologically active components and/or other components from the wound dressing that aid in proliferation or that are favorable to the wound healing process are returned to the wound; a device for moving fluid through at least the wound dressing and the means for fluid cleansing; a means for supplying thermal energy to the fluid provided to the wound ***so as to maintain the wound at a temperature between 34 and 40 degrees Celsius*** to optimize the metabolic activities of physiologically active components within the wound dressing and promote wound healing, and ***a means for bleeding the fluid flow path to bleed fluid from the recirculation tube***, as set forth in Claim 1.

Again, as discussed and agreed to during the interview, Swanbeck does not disclose or suggest a means for bleeding the fluid flow path to bleed fluid from the recirculation tube, as set forth in Claim 1.

Further, Applicants submit that Swanbeck does not disclose, suggest, or render obvious a means for supplying thermal energy to the fluid provided to the wound so as to maintain the wound at a temperature between 34 and 40 degrees Celsius to optimize the metabolic activities of physiologically active components within the wound dressing and promote wound healing.

The Office Action states at page 7 that it would have been obvious to one having ordinary skill in the art at the time the invention was made to maintain the temperature of the wound treatment fluids between 34 and 40 degrees Celsius, since it was known in the art that the optimal temperature range of the metabolic processes lies within the range of the body temperature that is

from 34 to 42 degrees Celsius. The Office Action refers to *The Columbia Electronic Encyclopedia*, and states that *The Columbia Electronic Encyclopedia* reference encompasses the claimed range.

However, Applicants submit that this rejection is improper or not sufficiently supported, for the following reasons. First, *The Columbia Electronic Encyclopedia* reference is not a proper prior art reference because *The Columbia Electronic Encyclopedia* does not have a publication date indicating that the reference was published prior to the date of invention of the present application.

Further, Applicants respectfully submit that the rejection based on *The Columbia Electronic Encyclopedia* is improper because *The Columbia Electronic Encyclopedia* is nonanalogous art. According to MPEP § 2141.01(a), a reference "must" be analogous to be relied on in a rejection under 35 U.S.C. 103. "[A] reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole." MPEP § 2141.01(a). Further, "[w]hile Patent Office classification of references and the cross-references in the official search notes of the class definitions are some evidence of "nonanalogy" or "analogy" respectively, the court has found "the similarities and differences in structure and function of the inventions to carry far greater weight.") (underlining added)). MPEP § 2141.01(a)(II), citing *In re Ellis*, 476 F.2d 1370, 1372, 177 USPQ 526, 527 (CCPA 1973).

In contrast with the invention of Claim 1, *The Columbia Electronic Encyclopedia* reference describes, in relevant portions, the effect of metabolism on body temperatures, and makes no mention of the effect of body temperature on wound healing (or any other aspect of wound healing). Therefore, assuming that *The Columbia Electronic Encyclopedia* reference was published prior to the date of invention of Claim 1, which Applicants do not concede, Applicants nonetheless submit that *The Columbia Electronic Encyclopedia* reference is non-analogous art, for the following reason. First, *The Columbia Electronic Encyclopedia* reference would not have commended itself to an inventor's attention because its disclosure is such a significant departure from the field of wound healing. *See* MPEP § 2141.01(a) (supra). Further, the invention of Claim 1 relates to an apparatus for irrigating, supplying thermal energy to, and cleansing wounds,

which is considerably different in structure *and* function as compared to the disclosure in *The Columbia Electronic Encyclopedia* reference, which merely discusses, in relevant portions, the effect of metabolism on body temperatures.

Finally, Applicants respectfully submit that *The Columbia Electronic Encyclopedia* reference does not disclose, teach, or render obvious the means for supplying thermal energy to the fluid provided to the wound so as to maintain the wound at a temperature between 34 and 40 degrees Celsius, as set forth in Claim 1. In fact, *The Columbia Electronic Encyclopedia* reference does not disclose or suggest any wound or body temperatures within the range of 34 to 40 degrees Celsius. *The Columbia Electronic Encyclopedia* reference merely states that, "[a]t environmental temperatures above 93°F; (34°C;), or at lower temperatures when metabolism has been increased by work, heat must be lost through the evaporation of the water in sweat," (underlining added) and that [t]he upper limit of body temperature compatible with survival is about 107°F; (42°C;), while the lower limit varies." (underlining added).

Therefore, Applicants submit that *The Columbia Electronic Encyclopedia* reference does not support the conclusion at page 7 of the Office Action that it was known in the art that the optimal temperature range of the metabolic processes lies within the range of the body temperature that is from 34 to 42 degrees Celsius, and that the rejection of Claim 1 is not properly supported.

Regarding Claims 2-5, 10-13, 15-18 and 20, respectfully stated, these claims are not anticipated, suggested, or rendered obvious by Swanbeck for at least the same reasons as for the claim or claims from which they depend, and also because they each recite further patentable distinctions.

For example, regarding Claim 13, the Office Action states at page 8 that "Swanbeck discloses the apparatus comprising the outlet tube fully capable of being connected to the waste reservoir." As discussed during the interview, Applicants submit that Claim 13 is not disclosed or anticipated by Swanbeck because Swanbeck does not show every element of each claim arranged as in each claim. *See* MPEP §2131. In addition to not disclosing the limitations of the claim or claims from which Claim 13 depends, Applicants submit that Swanbeck does not disclose, suggest, or render obvious that at least a portion of the fluid flowing through the outlet pipe is directed to a waste reservoir, as set forth in Claim 13.

Regarding Claim 16 and other claims, contrary to the conclusion at page 9 of the Office Action, Applicants submit that it would not have been obvious to one of ordinary skill in the art to heat the fluid in the fluid reservoir to a temperature approximately within the normothermic range to maintain the wound at an approximately normothermic range. Applicants submit that, for the reasons stated above for Claim 1, *The Columbia Electronic Encyclopedia* reference is not a proper prior art reference, is not analogous art and cannot therefore be used in a 35 U.S.C. 103 rejection, and further does not disclose, suggest, or render obvious the limitations set forth in Claim 16.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of Claims 2-5, 10-13, 15-18 and 20.

Claim Rejections – 35 U.S.C. 103 – Claims 6-8:

The Examiner rejected Claims 6-8 under 35 U.S.C. 103(a) as being unpatentable over Swanbeck in view of International Application Publication No. WO 00/50143 ("Burbank").

Respectfully stated, Claims 6-8 are not unpatentable over Swanbeck in view of Burbank because Burbank does not overcome Swanbeck's failure to disclose or suggest all of the limitations set forth in the claims from which Claims 6-8 depend (described above), and because the additional patentable limitations set forth in Claims 6-8 and the limitations of the claims from which they depend would not have been obvious to one of ordinary skill in the art in view of Swanbeck and Burbank at the time of the inventions.

New Claims Have Been Added:

New Claims 24-29 have been added. These claims are fully supported by the application as filed such that no new matter has been introduced by this Amendment. Regarding the art references cited in the Office Action, Applicants submit that Claims 24-29 are not anticipated or suggested by, or unpatentable over, the cited references for at least the same reasons as for Claims 1-8 and 10-23, and also because they each recite further patentable distinctions.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Docket No.	Serial No.	Title	Filed
SMNPH.003APC	10/576,263	WOUND CLEANSING APPARATUS WITH ACTIVES	09-Nov-2006
SMNPH.005APC	10/575,871	WOUND CLEANSING APPARATUS IN-SITU	29-Jan-2007
SMNPH.006APC	10/575,870	WOUND CLEANSING APPARATUS WITH SCAFFOLD	17-Apr-2006
SMNPH.007APC	10/599,720	WOUND CLEANSING APPARATUS WITH STRESS	06-Oct-2006
SMNPH.007C1	11/957,860	WOUND CLEANSING APPARATUS WITH STRESS	17-Dec-2007
SMNPH.008APC	10/599,722	DRESSING AND APPARATUS FOR CLEANSING THE WOUNDS	19-Sep-2008
SMNPH.009APC	10/599,725	APPARATUS FOR CLEANSING WOUNDS WITH MEANS FOR SUPPLY OF THERMAL ENERGY TO THE THERAPY FLUID	22-Sep-2008
SMNPH.010APC	10/599,728	APPARATUS FOR ASPIRATING, IRRIGATING AND/OR CLEANSING WOUNDS	03-Nov-2008
SMNPH.011APC	11/577,642	SIMULTANEOUS ASPIRATE & IRRIGATE & SCAFFOLD	23-Aug-2007
SMNPH.014APC	11/919,355	WOUND TREATMENT APPARATUS AND METHOD	26-Oct-2007
SMNPH.015APC	11/919,369	WOUND TREATMENT APPARATUS AND METHOD	26-Oct-2007
SMNPH.016APC	11/919,354	WOUND TREATMENT APPARATUS AND METHOD	26-Oct-2007
SMNPH.017APC	12/066,578	APPARATUS WITH ACTIVES FROM TISSUE	12-Mar-2008
SMNPH.018APC	12/066,730	APPARATUS WITH ACTIVES FROM TISSUE	13-Mar-2008

SMNPH.019APC	12/066,585	APPARATUS	12-Mar-2008
SMNPH.002C1	12/416,829	APPARATUS FOR ASPIRATING, IRRIGATING AND CLEANSING WOUNDS	01-Apr-2009

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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AMEND

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